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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,824	11/14/2003	Alan E. Nash	3282/30US	2581

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ADAMS EVANS P.A.
301 SOUTH TRYON STREET, SUITE 2180
TWO WACHOVIA CENTER
CHARLOTTE, NC 28282-1991

EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,824	NASH, ALAN E.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are pending and included in the prosecution.

Specification

1. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b). The abstract in an application filed under 35 U.S.C. 111 may not exceed 150 words in length.

2. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. The use of the trademark "Dr. Scholl's", "Mylar" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claims recite "medicated pad of hydrocolloid". The specification gives no guidance to one of ordinary skill in the art regarding such a medicated pad. The specification does not describe what medication included in the hydrocolloid pad.

The expression "medicated hydrocolloid pad" without description of any medication in the hydrocolloid pad does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The language "medicated" recited without any description of any medicines included in the hydrocolloid pad does not meet the written description requirement as one of ordinary skill in the art could not recognize what medication in the hydrocolloid pad from the mere recitation of the "medicated hydrocolloid pad". The claims neither provide the elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted in terms of medication included in the hydrocolloid pad. The expression "medicated hydrocolloid pad" could encompass myriad of medications and

applicants claimed expression represents only an invitation to experiment regarding possible medications.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. *Vas-Cath Inc. v Mahurkar*, 19 USPQ 2d 1111..

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the expression “medicated hydrocolloid pad” does not set forth the metes and bounds of the claim. Recourse to the specification does not define the expression “medicated”.

Regarding claim 1, the phrases "such as" render the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 2, the claim recites the limitation "M treatment" in the 1st line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0013300 (300) in view of US 6,303,140 ('140) or vise versa, and further combined teachings of US '300 and US '140 in view of US 2005/0042267 ('267).

The present claims are directed to box comprising multiple patches some contain salicylic acid and some are not.

US '300 teaches kit in a package for treating scar wherein the kit comprising composition comprising salicylic acid to be applied topically to the skin and thermal insulating material to cover the area of the skin after contacted the skin with the composition to elevate the scar temperature and bring about improvement in the size of the scar (paragraphs 0019, 0058, 0059, 0062, 0063, 0111). The thermal insulating material can be a sponge made of collagen, which reads on the medicated hydrocolloid patch and also reads on foam cover (paragraphs 0064, 0076, 0086, 0087). The reference teaches using various hydrogel combinations in sequence that suggests AM and PM patches (0088).

The difference between the present claims and US '300 is that US '300 does not teach the composition comprising the salicylic acid in the form of a patch and does not teach the amount of salicylic acid as instantly claimed.

US '140 teaches a medicated plaster comprises salicylic acid in amount preferably from 36-44% (abstract; col.3, lines 25-32). The plaster has advantage of efficaciously release the active agent into the skin at a sufficient rate and/or quantity to treat or remove corns and calluses (col.1, lines 45-48). The medicated plaster is applied according to a regimen effective to remove corns or calluses and typically the medicated plaster is covered with an enclosed cushion or pad (col.5, lines 4-14). The medicated plaster is further attached to a substrate to provide occlusive properties and dimensional strength to the plaster, i.e. backing (col.4, lines 33-38).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide sequence of treatment comprising applying topical composition comprising salicylic acid to the skin then cover it with hydrogel sponge as disclosed by US '300, and replace the topical composition with a medicated plaster comprising 36-44% salicylic acid as disclosed by US '140, motivated by the teaching of US '140 that application of that amount of salicylic acid in a medicated plaster has advantage of efficaciously release the active agent into the skin at a sufficient rate and/or quantity to treat or remove corns and calluses, with reasonable expectation of treating corns or calluses using medicated plaster that efficaciously release the active agent into the skin at a sufficient rate and/or quantity and covered with hydrogel sponge. In addition one having ordinary skill in the art would have added substrate to the

hydrogel disclosed by US '300 as disclosed by US '140, motivated by the teaching of US '140 that the substrate provides occlusive properties and dimensional strength to the plaster, with reasonable expectation of having patches of sponge hydrogel having substrate with sufficient strength and occlusive properties to cover the medicated patches of salicylic acid.

Vise versa, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medicated plaster comprises salicylic acid in amount preferably from 36-44% covered with cushion or pad as disclosed by US '140, and apply a hydrogel sponge after the application of salicylic acid as disclosed by US '300, motivated by the teaching of US '300 that such a hydrocolloid hydrogel elevates the skin temperature underneath it and brings about improvement in the size of the scar, with reasonable expectation of having skin treatment comprising applying salicylic acid patch covered with a cushion or pad followed by application of hydrocolloid hydrogel sponge to elevate the temperature of the skin underneath the sponge with the benefit of improving the underlying skin condition.

The combination of US '300 and US '140 does not teach the kit comprises plurality of patches.

US '267 teaches system comprising plurality of patches that provide different types of therapy are packaged together in one container, and plurality of patches are held by one carrier (abstract; figures 3 and 5; paragraphs 0011, 0013, 0029, 0033, 0041). The system makes it easier for the user or therapist to readily choose an appropriate therapy (paragraph 0012).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide treatment kit comprising patches comprising salicylic acid, protective cushions or pads, and patches to cover the salicylic acid patches as disclosed by the combined teachings of US '300 and US '140, and package all the patches in one container as disclosed by US '267, motivated by the teaching of US '267 that such a system packaging plurality of patches having different materials makes it easier for the user or therapist to readily choose an appropriate therapy, with reasonable expectation of having package comprising patches containing salicylic acid covering pads, and hydrogel sponges all in one container with the benefit of easiness for the user or therapist to readily choose an appropriate therapy.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2004/0202706 teaches kit comprising topical composition including salicylic acid and hydrogel patches to occlude the composition.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

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ISIS GHALI
PRIMARY EXAMINER